

REMARKS

The claims under examination now are 1-25 and 32, claims 26-31 having been withdrawn from further consideration because of a restriction requirement.

The objection to claim 15

The objection to the multiple dependency has been overcome by the foregoing amendment.

Support for the new claim 32

The support for this claims is found at page 20, lines 42-46.

The rejections under 35 USC 112, first paragraph¹

The examiner rejects the subject matter of claims 1, 5, 12-14 and 16-25 as violating the "enablement" and (presumably) the "written description" requirements of § 112, 1st paragraph. The examiner takes the position that "polyether containing compounds" and "copolymerizable monomers" as well as the language "at least partial hydrolysis" are broader than the enabling disclosure. Applicants respectfully disagree.

In support of his position the examiner cites *University of California v Eli Lilly*, 43 USPQ2d 1398 (Fed.Cir. 1997) (*Lilly*). However, *Lilly* is inapposite to the facts in this case. It must be kept in mind that applicants' claims are *process* claims. As stated in *In re Sarett*, 327 F.2d 1005, 140 USPQ 474, 486 (CCPA 1964):²

Broad inventions can be defined only by broad claims. ***It is certainly not incumbent on

¹ According to *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971), the second paragraph should be considered *first* to determine whether the skilled worker would have understood what the claims cover (in light of the specification, of course) and *then* look to the enabling requirement of the first paragraph.

² The board has held in the past that process claims are not held to the same rigid standard as compound claims regarding compliance with the first and second paragraphs of § 112. Cf. *Ex parte Peter*, 59 USPQ 107 (Bd.App. 1943). The patentability of the non-examined composition claims is left for another day.

an appellant who has made a broad process invention and *In re Cavallito*, 282 F.2d 363, 127 USPQ 206 (CCPA 1960) (*Cavallito* 2). to demonstrate the operativeness of every substance falling within the scope of the broad claims to which he is entitled. In the instant case the research to do this would quite evidently be endless.

Lilly, unlike *Sarett* and the instant claims, held that "a cDNA is not defined or described by the mere name 'cDNA.'" Indeed, on the same page of *Lilly* cited by the examiner, *consistent* with *Sarett* the court noted:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under § 112, ¶ 1, by showing of enablement of a representative number of species within the genus. See *Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "are *not* required to disclose every species encompassed by their claims even in an unpredictable art" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may provide an implicit description upon which to base generic claim language.")

Applicants are aware of no law to the effect that merely because a claim "broadly encompasses those known and unknown compounds as of the instant filing date" (emphasis original) it fails to comply with § 112, first paragraph. Cf. *In re Cavallito*, 282 F.2d 363, 127 USPQ 206 (CCPA 1960) at 127 USPQ 206:

The appealed claim covers a very large number of chemical compounds which may be developed in the future and which will possess the structure which appellants assert and the Patent Office admits is a novel structure. Due to the nature of chemical compounds and chemical processes it is conceivable that an almost infinite number of compounds may be developed by chemists if they have before them the teachings which appellants assert to be new in this field, namely, the particular structure and molecular arrangement of their new compounds. It seems to us that it is proper for the Patent Office to examine such assertions of patentability with great care but, when that has been done, the standards by which the ultimate determination of patentability or unpatentability should be made are those standards which Congress has provided in the patent statutes.

The examiner does not make clear how applicants' disclosure lacks a "recitation of a representative number..." (*Lilly* and *Cavallito*, *supra*) of compounds. Indeed,

looking at applicants disclosure teaches, in *addition* to the *many* examples:

Compounds	Location in Disclosure, Inter Alia
Monomers a)	Page 9 line 2 to 11, line 6
Polyether containing compounds b)	Page 2, line 22 to page 8, line
Optional co-monomers c)	Page 10, line 5 to page
The partial hydrolysis	Page 20, lines 28, et seq.

Of course if any of the compounds included within the claims would render the process inoperative for the purpose of the invention -- "improv[ed] hold or elasticity of a hairstyle" -- they are *necessarily* excluded by the claims. See, inter alia, *In re Bowen*, 492 F.2d 859, 181 USPQ 48 (CCPA 1974) and *In re Dinh-Nguyen*, supra, at 181 USPQ 48 ("It is not a function of the *claims* to specifically exclude...possibly inoperative substances..."). Similarly, if the degree of partial hydrolysis would render the process inoperative for its purpose, it likewise is excluded.

To be sure, the limitation of the claims -- "improv[ed] hold or elasticity of a hairstyle" -- is "necessary to give life, meaning, and vitality" to the claims, as discussed in *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202 (Fed.Cir. 2002). Cf., inter alia, the table on page 35 of the instant specification regarding these properties.

The examiner purports that "undue experimentation" would be required to utilize the invention has claimed. However the examiner has not sustained his burden of going forward to establish undue experimentation. Moreover, Some experimentation, even if complex, is permitted. *M.I.T. v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

The examiner further proposes that the claims are "functional at the point of

novelty," again citing *Lilly* at 43 USPQ2d 1406 to support his contention that "polyether containing compounds" and "copolymerizable monomers" as well as the language "at least partial hydrolysis." However, these limitations are *not* at all "functional." Rather "polyether containing compounds" and "copolymerizable monomers" are not "functional" but rather each are classes of compounds adequately described in the specification. In the same vein, "at least partial hydrolysis" is a description (fully supported as noted above) of the final product used in the method claim." In any event, there is nothing intrinsically wrong with "functional language." *In re Caldwell*, 319 F.2d 254, 258, 138 USPQ 243 (CCPA 1963); *In re Swinehart*, 169 USPQ 226, 228 & n.4 (CCPA 1971).

Unlike the facts here, *Lilly* (ibid) held that a particular limitation -- "mammalian insulin cDNA," without more (under the facts of this case), "does not suffice to define the genus because it is only an indication of the gene does, rather than what it is." Under the facts in the instant application, the skilled worker would understand what is encompassed by the limitations in question, because of the more than adequate disclosure discussed above.

Moreover, the examiner has not sustained his burden of establishing non compliance with the statute. *In re Gazave*, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); *In re Gardner*, 475 F.2d 1389, 177 USPQ 396, 397 (CCPA 1973); *In re Budnick*, 537 F.2d 535, 537, 190 USPQ 433, 423 (CCPA 1976) (Burden always on the examiner to show non-compliance.).

Accordingly, the specification complies with the written description and enabling requirement of § 112, 1st paragraph.

The rejection under 35 USC 112, second paragraph

According to the examiner "partial hydrolysis [emphasis original] " is indefinite. However, the examiner hasn't explained *why* the expression would have not been able to the scope of the claim. As explained *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd.Pat.App.&Int. 1989) "In rejecting a claim under the second paragraph of 35 USC 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims."

Further, as explained in *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (1971), The proper inquiry...

is merely to determine whether the claims do, in fact set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed -- not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by the ordinarily level of skill in the pertinent art.

As explained above, there is ample disclosure to inform the skilled worker how to carry out the process of the instant claims.

The rejection under 35 USC § 102

According to the examiner, the claims are anticipated by Blankenburg et al. (US 6,403,074, equivalent to WO/99/04750) on the ground that monomers (a) of the reference, $X-C(O)R^7=CHR^6$, include applicants' monomer a). That is not correct. Blankenburg's formula reads on acrylic acids and derivatives (i.e. the double bond is in

the acid part of the ester) whereas applicants claim vinyl ester of C₁-C₂₄-carboxylic acids (i.e. the double bond is in the alcohol part of the ester).

Consequently, the produced polymers are distinct, and after having performed the (partial) hydrolysis according to applicants' claims, applicants' polymers have vinyl alcohol units in the polymer backbone, whereas Blankenburg would have carboxylic acid units.

It is thus clear that Blankenburg et al. does not anticipate--or for that matter render obvious--applicants invention as claimed.

The double patenting rejections

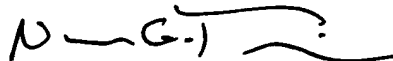
Applicants hereby file terminal disclaimers as to US Patent Nos. 6,403,074 and 6,770,293. This should overcome the double patenting rejections of these patents.

Conclusion

For the reasons set out above, allowance is respectfully solicited.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF



Norman G. Torchin
Reg. No. 34,068

1350 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 659-0100
NGT/kas